

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

_____)	
IN RE WELLBUTRIN SR/ZYBAN)	
ANTITRUST LITIGATION)	
)	Master File No. 02-CV-4398
)	
THIS DOCUMENT RELATES TO:)	Judge Bruce W. Kauffman
)	
ALL ACTIONS)	ORAL ARGUMENT REQUESTED
_____)	

**DEFENDANTS' REPLY MEMORANDUM IN
SUPPORT OF MOTION TO DISMISS**

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INTRODUCTION AND SUMMARY

At the initial scheduling conference in this matter, the Court described the “gravamen” of Plaintiffs’ case as follows:

[I]t seems to me, this is a case where the plaintiffs are saying that the defendants have, in effect, abused their statutory right to commence litigation which automatically delays for 30 months the ability of the plaintiffs to buy generic drugs on the market place, which would be much less expensive than the name brand.

(Nov. 6, 2002 Tr. at 7.) Plaintiffs’ counsel replied, “That’s well put, your Honor.” (*Id.*) This is, in other words, a case that alleges harm to competition because a drug patent lawsuit, even a frivolous one, stays for thirty months the ability of the FDA to turn a tentative approval of an application to sell a generic drug into final approval.¹

Defendants’ Motion to Dismiss pointed out the flaw in that theory as applied to the allegations in this case: whatever potential there might be in the abstract for a thirty-month stay to delay generic entry, no delay had occurred here. The thirty-month stay as to the first filer, Andrx, expired in February 2002 – a year ago. Andrx’s continuing failure to obtain FDA approval has nothing to do with the thirty-month stay or GSK’s lawsuit against Andrx. Andrx is not authorized to sell generic versions of GSK’s bupropion products because and only because it has not submitted an application that FDA has seen fit to approve. And because a first filer like Andrx enjoys 180 days of exclusivity, FDA cannot give final approval to other applications – an outcome that, again, has nothing to do with what GSK has or has not done.

Plaintiffs have no real response. Their Opposition concedes that the thirty-month stay has expired (Opp’n at 2), that Andrx, the first company to file an application for FDA approval

¹ See also Compl. ¶ 6 (alleging litigation filed “for the purpose of triggering the 30-month stay”).

of generic versions of the drugs, has yet to obtain approval (Opp’n at 5), and that Andrx’s failure to obtain approval bars any other generic company from obtaining final approval to market the drugs (Opp’n at 2 n.4). The arguments they do mount either abandon the central theme of the Complaint – challenging litigation that injures plaintiffs by triggering a thirty-month stay – or are simply wrong.

First, Plaintiffs concoct an entirely new theory as to how “Defendants could have unreasonably restrained trade.” (Opp’n at 2) (emphasis added). Their new idea is that Defendants “may have” entered into “an anticompetitive settlement agreement with Andrx for it to pursue its Abbreviated New Drug Application (‘ANDA’) so as to prevent other generics from receiving final FDA approval to come to market.” (Id.) It is this unpled canard that Plaintiffs assert should keep their case alive. They say that “[i]n the absence of discovery which may disclose that Defendants have entered into a similar arrangement with Andrx or Watson, this Court should refrain from reaching the conclusion proffered by Defendants.” (Id. at 15.) But Plaintiffs’ Complaint does not allege this theory and cannot fairly be read to encompass this theory. If Plaintiffs’ counsel want to prosecute a conspiracy case, they should be required to sign their names to a complaint whose allegations, as required by Fed. R. Civ. P. 11, “have evidentiary support or, if specifically so identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery.” Indeed, Plaintiffs’ new theory of a GSK-Andrx conspiracy contradicts the central premise of the Complaint – that Andrx was the victim of GSK’s allegedly baseless lawsuit.

Second, Plaintiffs ask this Court not to take judicial notice of a fact that they concede to be true: that Andrx, the first filer, has not yet obtained FDA approval. (Opp’n at 5 (conceding that “Andrx . . . has yet to receive FDA approval”).) Plaintiffs concede that the report cited by

Defendants for this proposition is a published report of an administrative agency. (Id. at 11.)

Thus, even if Plaintiffs had not admitted the truth of the fact, it would be proper for the court to take judicial notice of it. Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1197 (3d Cir. 1997). Plaintiffs' argument that the Court cannot take judicial notice of that fact because "[t]he public does not have unqualified access to the documents upon which the report is based" is untenable. (Opp'n at 11.)

Third, without attempting to make a causal link between the challenged patent litigations and the injuries Plaintiffs allegedly have suffered, Plaintiffs point to their allegations that Defendants "engaged in a series of anticompetitive and unlawful actions" and that Plaintiffs have "been forced to pay supra-competitive and artificially high prices for Wellbutrin[®] SR and/or Zyban[®]" and argue that these are more than sufficient to satisfy causation and damage requirements. (Opp'n at 12-13.) Plaintiffs' argument here simply ignores the law that elsewhere Plaintiffs recognize is controlling, which requires a complaint to contain factual allegations that "plainly establish the required causal connection" between the alleged conduct and the alleged harm. (Opp'n at 13 (quoting In re Warfarin Sodium Antitrust Litig., 214 F.3d 395, 402 (3d Cir. 2000)).) Their bare assertion that injury somehow resulted from unspecified conduct (i.e., "a series of anticompetitive and unlawful actions" (Opp'n at 18)) is not sufficient to avoid dismissal for lack of causation.

Finally, Plaintiffs argue that there is no heightened pleading requirement for antitrust cases, that all they are required to provide is a "short and plain statement of the claim," and that their allegation that Defendants "engaged in a series of anticompetitive and unlawful actions that ultimately extended exclusivity on the sale of Wellbutrin and Zyban" is sufficient to satisfy all pleading obligations, including the obligation to plead that the alleged act proximately caused the

alleged injury. (Opp’n at 15-18.) This argument misconstrues the Motion to Dismiss. GSK is not arguing that the Complaint lacks a short and plain statement of causation. GSK is saying that the short and plain statement found in the Complaint – that the thirty-month stay triggered by GSK’s patent suit against Andrx delayed generic entry – is wrong as a matter of law. Plaintiffs’ attempt to find causation elsewhere, e.g. in a “conspiracy” that is not in their Complaint, is a concession that the allegations of the Complaint are deficient.

ARGUMENT

I. Plaintiffs Cannot Base the Causation Element of Their Case on Conspiracy Theories That Are Not Pled in Their Complaint

Plaintiffs begin their Opposition with a section entitled “Introduction and Facts,” apparently to distinguish the “facts” described in this section from those described in the next section, which is titled “Factual Allegations of the Complaint.” The “facts” contained in the “Introduction and Facts” section are not alleged in the Complaint. Rather, the “facts” in the “Introduction and Facts” section are Plaintiffs’ speculations about what Defendants “could have” done, what Defendants “may have” done, and what bad acts other companies, not named defendants here, have committed in the past.

The conspiracy theory that Plaintiffs imagine in this section is that Defendants “may” have entered into an anticompetitive and secret settlement with Andrx, the purpose of which may have been to keep other generics from receiving FDA approval. And, Plaintiffs conjecture, Defendants’ patent infringement settlement with Watson, the second filer, may have prevented Watson from entering into a joint venture that it “could create” with Andrx to jointly enter the market. As support for these unalleged (and untrue) hypotheses, Plaintiffs say that “Andrx has allegedly engaged in this type of behavior before,” that “in the past . . . Watson has accepted

money to restrain generic competition,” and that Defendants’ settlement with Watson is “secret.” (Opp’n at 23, 5.)² Plaintiffs profess surprise that Andrx has yet to obtain FDA approval and speculate that Andrx’s failure to obtain approval must be because “something besides truly competitive market forces” is “afoot.” (*Id.* at 6.)

This conspiracy is nowhere to be found in Plaintiffs’ Complaint – not directly, not indirectly, and not through veiled allusion.³ The Complaint contains four counts. In each of the counts, the only specific conduct alleged to have violated the law is the filing of patent suits:

- Count I alleges monopolization (i.e., single firm conduct) under Section 2 of the Sherman Act. The only specific conduct alleged to violate Section 2 is “improperly filing and prosecuting a series of patent infringement actions against companies seeking to market an extended release bupropion hydrochloride product.” (Compl. ¶ 128.)
- Count II alleges monopolization under state laws, and, again, the only specific conduct alleged to support that claim is “improperly filing patent infringement actions against generic manufacturers seeking to obtain approval to sell generic versions of Wellbutrin SR and/or Zyban.” (Compl. ¶ 133.)

² No negative inference can be drawn from the filing of settlement papers under seal. If any inference is to be drawn from GSK’s court-sanctioned settlement with Watson, it should be that the settlement is lawful. A federal district judge reviewed the settlement and dismissed the case “based upon the materials submitted to this Court,” which included the settlement and resulting supply agreement. Stipulated and Agreed Order of Judgment at ¶¶ 12-13, Glaxo Wellcome, Inc. v. Watson Labs., Inc., C-1-01-0076 (July 11, 2001) (Opp’n Ex. B). Furthermore, GSK has agreed to produce “materials that constitute any patent infringement settlement with any entity (including Watson Pharmaceuticals) relating to Wellbutrin SR and/or Zyban or its generic equivalent” once an appropriate protective order is in place. (Proposed Order Regarding Initial Discovery Proceedings ¶ 2.) Since at least November, GSK’s counsel have repeatedly offered to assist Plaintiffs in discussions with the generic companies to expedite an agreement regarding a protective order. Plaintiffs have declined our help. GSK stands ready immediately to produce the Watson settlement papers *in camera* to the Court, *ex parte*, and to produce them to Plaintiffs once such a protective order is in place. While GSK continues to believe the GSK/Watson settlement papers are irrelevant to the case as pled in the Complaint, if the Court wishes to consider the Watson Settlement and take judicial notice of it as a court record, it could.

³ Indeed, Plaintiffs’ speculation about a conspiracy is inconsistent with the Complaint, which alleges that Andrx, far from cooperating with GSK, filed a motion for summary judgment against GSK, won it, and is now defending it on appeal in the Federal Circuit. (Compl. ¶¶ 94-98.)

- Count III alleges that “Defendants engaged in unfair competition or unfair, unconscionable, deceptive fraudulent acts or practices in violation of [various] state consumer protection statutes . . . when they filed baseless patent infringement actions against Andrx and other generic manufacturers in order to prevent the FDA from granting final approval of pending applications of would-be competitors to market generic Wellbutrin SR and Zyban.” (Compl. ¶ 161.)
- Finally, Count IV, for unjust enrichment, charges no particular conduct other than “the unlawful and inequitable acts alleged in this Complaint.” (Compl. ¶ 208.)

Yet Plaintiffs advance their conspiracy yarn as the sole basis on which the Court should deny Defendants’ Motion to Dismiss. (Opp’n at 15 (“In the absence of discovery which may disclose that Defendants have entered into a similar arrangement with Andrx or Watson, this Court should refrain from reaching the conclusion proffered by Defendants.”).) Plaintiffs, in other words, are asking this Court not to dismiss a deficient Sherman Act Section 2 monopolization case on the basis of inconsistent Sherman Act Section 1 conspiracy charges that were nowhere leveled in the Complaint and as to which they have not sued the conjectured co-conspirators, despite their duty to represent the interests of the putative class vigorously.

As (then Chief) Judge Lord has noted “[w]hile antitrust complaints are not subject to especially stringent pleading . . . neither are they exempt from the federal rules.” Sims v. Mack Truck Corp., 488 F. Supp. 592, 608 (E.D. Pa. 1980). The Third Circuit has stated that a bare bones allegation of antitrust conspiracy without any supporting facts does not meet Rule 8(a)’s requirement of “a short and plain *statement* of the claim showing that the pleader is entitled to relief.” Pennsylvania ex rel. Zimmerman v. Pepsico, Inc., 836 F.2d 173, 179 (3d Cir. 1988) (quoting Fed. R. Civ. P. 8(a)) (finding that plaintiff’s “rights rise no higher than the facts it has alleged, and that the defendants cannot be said to have violated the antitrust laws in ways that have not been alleged”) (emphasis in original). An allegation of “unspecified contracts with unnamed other entities to achieve unidentified anticompetitive effects does not meet the

minimum standards for pleading conspiracy in violation of the Sherman Act.” Garshman v. Universal Res. Holding Inc., 824 F.2d 223, 230 (3d Cir. 1987) (dismissing Sherman Act Section 2 claims where no act that could support a monopolization allegation was pled in the complaint). A complaint is deficient if it does not identify the “nature, formation and membership of the conspiracy.” Pao v. Holy Redeemer Hosp., 547 F. Supp. 484, 491 (E.D. Pa. 1982) (dismissing Sherman Act conspiracy claims where the complaint did not identify the nature, formation and membership of the alleged conspiracy or set forth specific factual allegations concerning the character of the conspiracy). Furthermore, “[a]lthough detail is unnecessary, the plaintiffs must plead the facts constituting the conspiracy, its object and accomplishment.” Advanced Lifeline Serv., Inc. v. N. Health Facilities, Inc., C.A. No. 97-3757, 1997 U.S. Dist. LEXIS 19550, at *20 (E.D. Pa. Dec. 9, 1997) (courts should not “shy away from dismissing an antitrust [conspiracy] claim that is vague and conclusory in nature”).

The Complaint in this case does not even contain a count for conspiracy, let alone any facts to support a conspiracy claim. Instead, by Plaintiffs’ own admission, the Complaint in this regard is limited to the allegation that GSK has “engaged in a series of anticompetitive and unlawful actions.” (Opp’n at 2.) The Third Circuit has made clear that “[i]t is one thing to set forth theories in a brief; it is quite another to make proper allegations in a complaint. . . . ‘[I]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss.’” Pepsico, 836 F.2d at 181 (quoting Car Carriers, Inc. v. Ford Motor Co., 745 F.2d 1101, 1107 (7th Cir. 1984)).

What’s more, Plaintiffs have admitted to the Court that they did not file a conspiracy case. At the November 6, 2002 scheduling conference, Plaintiffs informed the Court that they had requested a copy of the agreement between GSK and Watson settling that patent

infringement action. Plaintiffs indicated that “one of the issues that has been a hot topic . . . in the brand name generic drug arena has been whether resolutions of patent infringement litigation are themselves anti-competitive depending on the nature of the underlying arrangement between the parties.” (Tr. at 34.)⁴ However, when the Court asked Plaintiffs if they were suggesting an intent to monopolize by settling a case that had no merit, Plaintiffs responded, “Well, we’re not saying it yet.” (Id. at 37.)

Plaintiffs are trying to say it now, but not because they have any more facts to support this charge than they had on November 6. They are claiming conspiracy in an effort to save a Complaint that they now realize inadequately alleges causation. If Plaintiffs wish to convert this case from a Sherman Act Section 2 unilateral conduct case into a Sherman Act Section 1 conspiracy case, they should file a new complaint, subject to the requirements and sanctions of Rule 11.⁵ As the Supreme Court has concluded, “[I]t is not . . . proper to assume that [a plaintiff] can prove facts that it has not alleged or that the defendants have violated the antitrust laws in ways that have not been alleged.” Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters, 459 U.S. 519, 526 (1983).

⁴ It is worth noting that even if the Watson settlement were to reflect some unlawful conspiracy between GSK and Watson (which it does not), it would be of no moment, for, as Plaintiffs themselves have noted, Andrx’s failure to enter the market “prevent[s] other generic companies from entering the market” until Andrx’s 180 days of exclusivity expire. This result arises from the Hatch-Waxman Act and is independent of anything GSK might do. (See Opp’n at 2).

⁵ This is not simply a matter of form. The conspiracy charges are not true. Rule 11 does not announce a policy that if you can imagine it, you can allege it. There must be some factual basis. There is none here. Andrx’s SEC filings and statements to analysts are that it is vigorously pursuing FDA approval. Andrx has, moreover, entered into an FTC consent decree that prohibits agreements such as those that Plaintiffs imagine. In re Hoechst Marion Roussell et al., No. 9293, Parts III and IV, at <http://www.ftc.gov/os/2001/04/hoechstdo.pdf>. (last visited on Feb. 3, 2003) (attached as Ex. 1).

II. This Court Can and Should Take Judicial Notice of the Fact – Available in a Published Report of an Administrative Agency and Conceded by Plaintiffs – That FDA Has Not Approved Andrx’s ANDA

GSK has asked that the Court take judicial notice of a single fact, which Plaintiffs have admitted and which appears in what Plaintiffs concede is a public government document: that FDA has not approved Andrx’s ANDA. Plaintiffs spend pages arguing that it would be improper to take such notice,⁶ but they concede the truth of the matter. (Opp’n at 5 (Andrx “has yet to receive FDA approval”).)⁷ Plaintiffs also concede that it is proper to take judicial notice of “published reports of administrative bodies.” (Opp’n at 10 (citing Pension Benefit Guar. Corp., 998 F.2d at 1197).) Plaintiffs argue, however, that it is inappropriate to consider the FDA Listing of New & Generic Drug Approvals because “[a]lthough that report is publicly available on the internet, the ANDA filed by Andrx . . . and all the correspondence between Andrx and the FDA is not subject to disclosure.” (Opp’n at 11.)

Plaintiffs are wrong. The FDA Listing of New and Generic Drug Approvals is, Plaintiffs concede, a “report” that is “publicly available on the internet.” (Opp’n at 11.)⁸ It is the conclusion in this report, the absence of approval for any ANDA applicant other than Eon, that GSK asks this Court to take judicial notice of. The FDA publication meets the Pension Benefit

⁶ Plaintiffs also take issue with GSK’s citation to a presidential press release. This material is not essential to the resolution of the motion to dismiss, but merely provided helpful background information.

⁷ Moreover, Plaintiffs’ Complaint alleges that Eon has received tentative FDA approval (Compl. ¶ 83), but conspicuously does not allege – because it cannot – that Andrx has received FDA approval.

⁸ The FDA Center for Drug Evaluation and Research, which maintains the Listing, describes it as “an alphabetical listing of all prescription drugs approved during 1998 through 2003 [that] is updated on a daily basis and contains links to labels, approval letters, and reviews.” CDER, Information about the Products We Regulate, at <http://www.fda.gov/cder/drug/default.htm> (last visited Feb. 3, 2003) (attached as Ex. 2).

test of being a “published report[] of [an] administrative bod[y].” As such, it is proper for this Court to take judicial notice of the fact that, to date, Andrx has not received approval for its bupropion SR ANDA.⁹

III. The Complaint Must Be Dismissed for Want of Causation Because Plaintiffs Make No Credible Assertion That the Thirty-Month Stay Triggered by the Filing of GSK’s Patent Suits Injured Them

Only Section B of Plaintiffs’ Opposition purports to address the causation arguments that Defendants’ Motion to Dismiss presented. (Opp’n at 12-15.) Yet even this section presents no credible theory to connect the conduct complained of – lawsuits that triggered a statutory thirty-month stay – and the alleged injury. Plaintiffs advance three arguments.

First, Plaintiffs point to certain allegations of the Complaint and suggest that these allegations are sufficient to satisfy their pleading obligations:

- Defendants “engaged in a series of anticompetitive and unlawful actions that ultimately extended exclusivity on the sale of Wellbutrin and Zyban,” thereby causing “no generic version of Wellbutrin [SR] and/or Zyban [to be] currently marketed in the United States.”
- Defendants’ unlawful conduct included “filing baseless lawsuits seeking to enjoin generic manufacturers from producing bioequivalent generic versions of Wellbutrin SR and/or Zyban.”
- Through “defendants’ unlawful, anticompetitive and inequitable methods, acts, and practices, and wrongful conduct in the conspiracies complained of,” Plaintiffs have been forced to pay “supra-competitive and artificially high prices for Wellbutrin SR and/or Zyban.”

⁹ Plaintiffs argue that the material GSK attached as Exhibit 1 to its Initial Memorandum was an “incomplete” copy of the FDA Listing of New and Generic Drug Approvals. GSK attached the pages listing approvals for all drugs beginning with the letter B, e.g., bupropion hydrochloride. By visiting the FDA’s website at <http://www.fda.gov/cder/approval/b.htm>, the Court can review the entire FDA Listing if it is so inclined. Plaintiffs have not suggested such an effort would be fruitful. Indeed, they agree that Andrx has not received approval. See CDER, New and Generic Drug Approvals: 1998-2003, at <http://www.fda.gov/cder/approval/b.htm> (last visited Feb. 3, 2003) (attached as Ex. 3).

(Opp’n at 13.) They studiously ignore, however, what they and this Court previously agreed was the gravamen of their case: the allegation that GSK brought baseless litigation “for the purpose of triggering the 30-month stay.” (Compl. ¶ 6 and page 1 above.)

None of the general allegations that Plaintiffs now cling to does what Plaintiffs concede a complaint must do: “‘plainly establish the required causal connection between [Defendants’] exclusionary anticompetitive conduct and the direct harm to [Wellbutrin and/or Zyban] purchasers.’ ” (Opp’n at 13 (quoting In re Warfarin Sodium Antitrust Litig., 214 F.3d at 402 (3d Cir. 2000)).) None of these allegations – or any other in the Complaint – shows a causal connection between the thirty-month stay triggered by the lawsuits and the absence of generic sellers of the drugs. In light of the facts alleged in the Complaint, and the single fact that Plaintiffs have conceded and that Defendants ask this Court to take judicial notice of, no such allegation is possible. Thus, while Plaintiffs assert that “Defendants’ argument to challenge causation here is strictly a factual defense, which is premature at this time and should be rejected by the Court” (Opp’n at 13), in fact the defense is based on the allegations of the Complaint and their insufficiency as a matter of law.

General allegations of “a series of anticompetitive and unlawful actions” (Compl. ¶ 1) – on which Plaintiffs apparently are relying because they realize that GSK’s patent infringement lawsuits did not in fact delay generic entry – are inadequate to state a claim on which relief can be granted. See Pepsico, 836 F.2d at 182 (antitrust “pleader may not evade the requirements of proper pleading ‘by merely alleging a bare legal conclusion’ ”) (quoting Car Carriers, 745 F.2d at 1108); Car Carriers, 745 F.2d at 1106-07 (accepting “bare legal conclusions” at the pleading stage “would be tantamount to providing antitrust litigation with an exemption from Rule 12(b)(6)”); Garshman v. Universal Res. Holding, Inc., 641 F. Supp. 1359, 1367 (D.N.J.

1986), aff'd, 824 F.2d 223 (3d Cir. 1987) (while a court must construe an antitrust complaint liberally, “[t]he court ‘must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed’ ”) (quoting Associated Gen. Contractors, 459 U.S. at 528 n.17); Pao, 547 F. Supp. at 491 (dismissing claims with prejudice where “the complaint . . . offers only uncertain clues as to plaintiff’s theory of liability and the facts which would support a finding of Sherman Act liability. It is simply not fair to the defendants . . . to permit litigation to go forward on the basis of such conclusory and speculative allegations.”); see also Schuylkill Energy Res., Inc. v. Pa. Power & Light Co., 113 F.3d 405, 417 (3d Cir. 1997) (finding, as to a Sherman Act Section 2 claim, that on 12(b)(6) motion to dismiss, the court is “not required to accept as true unsupported conclusions and unwarranted inferences”).

Second, Plaintiffs cite two cases that purportedly refute GSK’s causation arguments. They do not. In Bristol-Myers Squibb Co. v. Ben Venue Laboratories, 90 F. Supp. 2d 540 (D.N.J. 2000), a Hatch-Waxman patent infringement case, generic manufacturer Ben Venue (BV) filed antitrust counterclaims against Bristol-Myers Squibb (BMS) after the thirty-month stay had been triggered by BMS’s patent infringement suit. BMS moved for summary judgment on standing grounds, arguing that BV had received neither tentative nor final FDA approval. The court denied BMS’s motion for summary judgment. Given that the thirty-month stay was still pending, it was entirely possible that BV would obtain tentative FDA approval and then find final FDA approval blocked by the thirty-month stay. In contrast, the thirty-month stay against FDA approval of the first filer here, Andrx, expired before Plaintiffs filed this lawsuit and before Andrx had obtained favorable FDA review. Unlike Ben Venue, there is no set of facts possible

here in which the thirty-month stay will delay Andrx's entry. For that reason, Ben Venue is inapplicable.

Andrx Pharmaceuticals, Inc. v. Biovail Corp. Int'l, 256 F.3d 799 (D.C. Cir. 2001), cert. denied, 535 U.S. 931 (2002), is similar. There, Biovail, a generic firm, claimed that a conspiracy by the ANDA first filer to delay entry, and thereby delay the running of that firm's 180-day exclusivity period, unlawfully blocked FDA approval of Biovail's ANDA. First filer Andrx moved to dismiss on the ground that Biovail had not received tentative or final approval. The D.C. Circuit held that the district court had correctly dismissed the antitrust claim "for failure to sufficiently allege injury caused by the [challenged] agreement." Id. at 819. The court also held, however, that the district court should have granted the dismissal without prejudice to allow Biovail the opportunity to replead. Id. In that case, it was clear that facts could be pleaded that would show a causal connection between the challenged conduct and delayed generic entry because after the motion to dismiss was filed, FDA granted Biovail tentative approval but could not grant final approval "because of the exclusivity granted" to the first filer. Id. at 184 n.7 (quoting FDA approval letter to Biovail). Here, the thirty-month stay caused by GSK's lawsuit has expired without favorable FDA action on Andrx's ANDA. Here, there can be no credible allegation that a now-expired stay has delayed or will in the future delay Andrx's approval. See also Eon Labs. Mfg., Inc. v. Watson Pharms., Inc., 164 F. Supp. 2d 350, 356-57 (S.D.N.Y. 2001) (dismissal proper where generic could not allege how the defendant's conduct had forestalled the generic's entry).

Finally, Plaintiffs appear to say that it does not matter whether they have shown a causal connection between Defendants' patent litigations and the alleged harm, because discovery into their unalleged (and unfounded) "conspiracy" theory might turn something up. (Opp'n at 15.)

As discussed supra at 7-9, an unalleged conspiracy cannot support a deficient monopolization complaint.

IV. Plaintiffs' Other Claims Are Without Merit

A. Defendants' Motion to Dismiss Is Not Based on a Failure To Include a Short and Plain Statement of the Claim

Section C of the Opposition responds to an argument that Defendants did not make.

Plaintiffs say that “Defendants contend the Complaint should be dismissed because the Plaintiffs have not alleged each and every manner in which Defendants have prevented a generic version of Wellbutrin SR and/or Zyban from entering the market” (Opp’n at 15), and that “there is no heightened pleading standard” in antitrust suits (Opp’n at 18).

Defendants have made no such claims. Plaintiffs have in fact plainly alleged the conduct that they complain about – the filing of patent infringement lawsuits that triggered a thirty-month stay. Their claim must fail, but not because it is vague or insufficient to give Defendants notice of the conduct that is being challenged. Their claim must fail because it does not contain any allegation of causation other than that the thirty-month stay delayed generic entry. Once the Court takes judicial notice that the thirty-month stay expired a year ago and Andrx is still awaiting approval, it is clear that the causation Plaintiffs suggest is lacking.

Plaintiffs fall back in this section of their Opposition, as they do repeatedly, only to their conclusory allegation that Defendants “engaged in a series of anticompetitive and unlawful actions that ultimately extended exclusivity on the sale of Wellbutrin and Zyban.” (Opp’n at 18) (quoting Compl. ¶ 1.) As discussed supra at 6-8, even if such an allegation is read to refer to something other than filing lawsuits, it is deficient to state a claim for relief.

B. Causation Is a Required Element of Plaintiffs' State Law Claims

Causation is as much an element of Plaintiffs' seventy state law claims as it is an element of their federal claim, and GSK provided authority to that effect. Plaintiffs have no response as to the vast majority of these state claims. As to five of the seventy, however, Plaintiffs assert only that GSK's authority is not on point. They do not suggest, however, that there is contrary authority that would permit them to recover on these claims without establishing causation.

CONCLUSION

For the reasons stated above, the Complaint should be dismissed.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that the foregoing Defendants' Reply Memorandum in Support of Motion to Dismiss and the Appendix thereto were served on all counsel on February 3, 2003 as follows:

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